UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNTED STATES OF AMERICA et al.
ex rel. JULIE LONG,
Plaintiffs,

v. Civil Action No. 16-12182-FDS

JANSSEN BIOTECH, INC.,
Defendant.

MEMORANDUM AND ORDER ON RELATOR'S
MOTION FOR LEAVE TO PROPOUND REQUESTS FOR PRODUCTION IN EXCESS OF LIMIT SET BY LOCAL RULE 26.1 (#233) AND
MOTION TO COMPEL THE PRODUCTION OF DOCUMENTS REQUESTED IN HER THIRD SET OF REQUESTS FOR PRODUCTION (#235).

KELLEY, U.S.M.J.

I. Introduction.

This is a *qui tam* action alleging that a pharmaceutical company unlawfully provided free business advisory services to physicians who prescribed its medications, in violation of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), and caused physicians to submit false claims for reimbursement to Medicare in violation of the False Claims Act, 31 U.S.C. § 3729(a). Relator Julie Long, who worked as an "Area Business Specialist" ("ABS") for Janssen, alleges that Janssen Biotech, a company that manufactures and sells two infusible drugs, Remicade and Simponi ARIA, improperly employed teams of practice advisors, including relator, and hired outside consultants to provide services such as presentations, advice, and customized analyses to doctors

to assist them in running profitable infusion businesses (referred to here as "in-office infusion suites," or "IOIs").

The facts of the case and a detailed analysis of the claims in the Second Amended Complaint (#55) are set out in Chief Judge Saylor's Order and Memorandum on Defendant's Motion to Dismiss (#75) and will only be repeated here as necessary to put the motions at issue in context. In addition, the background concerning how discovery has unfolded in this case is discussed at length in this court's recent order on other discovery disputes (#282) and likewise will not be repeated here except as necessary.

At a hearing on October 1, 2021, Chief Judge Saylor ordered that the parties, after wrapping up phase one discovery, would litigate a bellwether motion for summary judgment. (#186 at 25.) The court cautioned that before the parties proposed a schedule for summary judgment, Janssen was to provide "complete fact discovery on the specific relator's claims, however we define that, however far up the chain it goes, whatever documents or depositions are required." *Id*. at 27. At a second hearing on October 22, 2021, the court emphasized that the summary judgment motion would test all elements of relator's claims. (#203 at 11-12.) Prior to this time, this court, in ruling on discovery motions, had limited relator's discovery in an effort to streamline the initial discovery phase of the case. (#282 at 4-5.) The question now is: how much more discovery practice should the parties engage in before moving to summary judgment?

II. The Present Motions.

Less than two weeks after learning that the parties were headed to summary judgment, on November 2, 2021, relator served Janssen with a third set of requests for production ("RFPs"). (#234-1.) This was followed by a motion for leave to propound RFPs in excess of the limit set by Local Rule 26.1(c), which limits parties to two separate sets of requests for production. (#233.)

Relator asked to propound two additional sets. (#234 at 9, 12.) The third set contains 21 additional requests which, according to relator, mainly focus on "whether the various IOI support services constitute illegal remuneration under the AKS and whether in providing the support … Janssen acted knowingly and willfully." *Id*. at 9. In addition, certain requests seek information about issues that, according to relator, have recently come to light in discovery. *Id*.

Plaintiff propounded a fourth set of requests for production on November 22, 2021. *Id.* at 12. These three new requests seek "documents and information regarding job descriptions, performance evaluations, and compensation structure for various employment positions that entail significant involvement or knowledge concerning Janssen's provision of the various types of IOI Support." *Id*.

Relator filed a motion to compel in connection with the third set of requests for production.[1] (#235.) Janssen opposed (#249) and the court held oral argument on the motions on January 13, 2022. (#276.) For the reasons set out below, the court allows #233, relator's motion to propound additional RFPs, and allows in part and denies in part #235, relator's motion to compel.

III. The Law.

Local Rule 26.1(c) provides that "[u]nless the judicial officer orders otherwise, the number of discovery events shall be limited for each side [to] 2 separate sets of requests for production." "Should a party exhaust the opportunities for any type of discovery events under L.R. 26.1(c), any requests that such party may make for additional . . . production of documents beyond that allowed

[1] Relator did not file a motion to compel production in connection with the fourth set of RFPs, therefore, the court does not address those requests. It appears that the parties were negotiating the scope of the requests in the fourth set of RFPs at the time the motions were filed, *see, e.g.*, #248 at 13, and the court assumes those negotiations were successful.

pursuant to L.R. 26.1(c) shall be by discovery motion." L.R. 26.2(b). In addition, Federal Rule of Civil Procedure 26(b)(2)(C) states:

> On motion or on its own, the court must limit the frequency or extent of discovery otherwise allowed by these rules or by local rule if it determines that: (i) the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive; (ii) the party seeking discovery has had ample opportunity to obtain the information by discovery in the action; or (iii) the proposed discovery is outside the scope permitted by Rule 26(b)(1).

Fed. R. Civ. P. 26(b)(2)(C).

IV. Discussion.

Janssen argues that the third set of RFPs "contains requests that are entirely duplicative or cumulative of past discovery requests, are not proportional to the needs of the case, or are outside the scope of phased discovery." (#249 at 8.)

RFP No. 38, for example, requests "[a]ll documents concerning business or marketing plans related to any of the various types of IOI Support provided." (#236-1 at 10.)[2] Janssen responds that it already searched for and produced relevant documents on this subject in response to relator's prior RFPs. (#249 at 8-9.) RFP No. 38 is allowed. If, as Janssen argues, Janssen has already produced all responsive information, it may notify relator of that fact.

RFP No. 39 requests "[a]ll documents concerning the assessment, evaluation, or analysis of the value physicians and physician practices derived from receiving any of the various types of IOI Support provided (including the presentations, resources, and programming utilized in connection with providing any IOI support)." (#236-1 at 10-11.) Again, as Janssen argues that it has already responded to this RFP (#249 at 8-9), this RFP is allowed, and Janssen may notify relator it has produced all responsive documents.

[2] The request, and RFP No. 39, excludes materials created by ABSs and Regional Business Managers who were not responsible for relator's territory. (#236-1 at 10-11.)

RFP No. 40 asks for "[a]ll documents concerning the assessment, evaluation, or analysis of any guidance or advisory opinion from the OIG related to the types of services that may implicate the AKS, including, but not limited to, product support services." (#236-1 at 11.) The court finds that this request is overbroad to the extent it asks for "all documents" relating to materials from the OIG related to *any* type of services. This request is allowed, but only with regard to the services at issue in this case.

RFP No. 41 requests "[a]ll documents concerning the assessment, evaluation, or analysis of whether any of the various types of IOI Support provided (including the presentations, resources, and programming utilized in connection with providing any IOI Support) constitute 'product support services,' as that term is used in guidance issued by OIG regarding the AKS." (#236-1 at 11.) In its opposition, Janssen argues broadly that relator's "new requests are duplicative of prior requests and seek information that Janssen has already produced." (#248 at 9-10.) It is not clear to the court that RFP No. 41 is not covered by previous requests. Nevertheless, the request certainly asks for relevant material and it is allowed. If it has already been provided, then Janssen may so inform relator.

RFP No. 42 asks for "[a]ll documents concerning the assessment, evaluation, or analysis of whether you should obtain an advisory opinion from OIG [U.S. Department of Health and Human Services Office of Inspector General] concerning whether any of the various types of IOI Support provided (including the presentations, resources, and programming utilized in connection with providing any IOI Support) implicate the AKS or any other law." (#236-1 at 11.) Janssen argues that it would not know how to find all documents in which it thought about requesting an OIG opinion, and that such materials are "far afield" of relevant issues in this case. (#276 at 40-41.) However, if someone at Janssen raised a red flag about whether any of the programs at issue

could run afoul of the AKS, they might very well have suggested reaching out to OIG for an advisory opinion. In this hypothetical scenario, Janssen's internal deliberations would be highly relevant to relator's claims and burden on scienter. Targeted keyword searches should assist Janssen in its search for these materials. The request is allowed.

RFP No. 43 requests "[a]ll documents concerning advice requested and/or received from attorneys or regulatory experts related to the lawfulness of providing any of the various types of IOI Support (including the presentations, resources, and programming utilized in connection with providing any IOI Support)." This request was in part addressed in a recent prior order of this court (#282) and in addition is related to pending motions before the court concerning whether Janssen has waived privilege (#263) and whether Janssen must produce a complete privilege log (#223). To the extent it requests documents that constitute legal advice or attorney work product, the court defers action on it at this time. It is otherwise allowed.

RFP No. 44 requests "[a]ll documents concerning the assessment, evaluation, or analysis of risks associated with providing any of the various types of IOI Support (including the presentations, resources and programming utilized in connection with providing any IOI Support), including, but not limited to, any assessment, evaluation, or analysis conducted as part of the Risk Assessment and Mitigation Planning Program undertaken in 2014." (#236-1 at 12.) The court does not know what the "Risk Assessment and Mitigation Planning Program undertaken in 2014" is. The court assumes that most if not all of the documents requested are privileged. For the same reasons stated above with regard to RFP 43, the court defers action on this request insofar as it requests privileged materials at this time. The request is otherwise granted.

RFP No. 45 requests "[a]ll documents concerning the assessment, evaluation, or analysis of whether providing any of the various types of IOI Support (including the presentations,

resources, and programming utilized in connection with providing any IOI Support) complied with Janssen's internal compliance policies, procedures, or guidance." *Id.* For the same reasons stated above with regard to RFP Nos. 43-44, the court defers action on this RFP at this time to the extent it requests privileged materials. Otherwise the request is granted.

RFP No. 46 requests "[a]ll documents concerning the assessment, evaluation, or analysis of whether providing any of the various types of IOI Support (including the presentations, resources, and programming utilized in connection with providing any IOI Support) complied with the PhRMA Code on Interactions with Health Care Professionals." *Id.* The court assumes that this RFP is relevant at least to Janssen's affirmative defense no. 14, "[r]elator's claims for relief are barred … because any and all actions taken by Janssen with respect to any of the matters alleged by [r]elator were taken in good faith and in accordance with established industry practice." (#83, Aff. Defense 14.) The request is allowed except to the extent it requests privileged materials.

RFP No. 47 requests "[a]ll Corporate Integrity Agreements to which [Janssen is or has] been a party." (#236-1 at 12.) Janssen responded at oral argument that this information is available online. (#276 at 36.) This request is therefore denied.

RFP No. 48 requests "[d]ocuments sufficient to show all investigations or audits that OIG or any other governmental body has performed or is performing concerning ABSs' practices or conduct in promoting and/or supporting the use and infusion of Remicade or Simponi ARIA." (#236-1 at 13.) Janssen stated that it has "already produced relevant communications with the government, or internal communications concerning government guidance about the legality of the programs at issue, *that were identified within the files of the current document custodians and relevant corporate repositories*." (#249 at 16.) (emphasis added.) RFP No. 48 requests more documents than those that have already been provided, and is allowed. Such documents should not

be difficult for Janssen to find and produce after a reasonable search for them. In its opposition Janssen agreed to "promptly produce any documents it receives from the government in the discovery process, which, as Janssen's objection indicates, is ongoing." *Id.* At oral argument on this matter, the court ordered Janssen to produce this information on a rolling basis, meaning, as it receives documents it should transmit them to relator, and should not wait until all communications with the government and documents received from the government are complete. (#276 at 42-43.)

RFP No. 49 requests "[a]ll documents concerning complaints or reports submitted to your legal department or compliance department alleging or asserting that any of the various types of IOI Support provided (including the presentations, resources, and programming utilized in connection with providing IOI Support) were unlawful, including documents concerning your subsequent investigation or review of such complaints or reports." (#236-1 at 13.) This request seeks relevant materials and is allowed to the extent it does not request privileged materials.

RFP No. 50 requests "[a]ll documents concerning this action that you provided or shared with any non-party to this case, including, but not limited to, any communications with any individual or company regarding any of the claims or defenses asserted in this action." *Id.* This request is overbroad and not clearly relevant to the current phase of discovery. The request is denied.

RFP No. 51 requests "[a]ll documents concerning the review or approval of a contract with a vendor or Outside Consultant to develop or provide any of the various types of IOI Support provided (including the presentations, resources, and programming utilized in connection with providing any IOI Support), including, but not limited to, Immunology Marketing Commercial Agreement Routing Slips (and equivalent forms)." *Id.* This request may be relevant at a later stage of the case, but is not relevant at this phase. The request is denied.

RFP No. 52 requests "[a]ll documents concerning your policies or guidance related to whether promotional materials, including the presentations, resources, and programming utilized in connection with any of the various types of IOI Support provided, could be left behind with customers or made accessible to all physicians on the Internet." *Id.* This request is allowed.

RFP No. 53 requests "[a]ll documents concerning the approval to make accessible to all physicians on the Internet any presentation, resource, or program utilized in connection with any of the various types of IOI Support provided." (#236-1 at 14.) This request is allowed.

RFP No. 54 requests "[a]ll documents concerning the decision to make any presentation, resource, or program utilized in connection with any of the various types of IOI Support provided nonbranded or unbranded." *Id.* This RFP was not specifically addressed in the parties' briefs or at oral argument and the court does not understand the relevance or importance of it. It is denied.

RFP No. 55 requests "[a]ll documents concerning meeting minutes, reports, recommendations, or discussions of advisory boards formed to provide advice or information related to any of the various types of IOI Support provided (including the presentations, resources, and programming utilized in connection with providing any IOI Support) or other educational, advisory, or support services that you furnished or considered furnishing to IOI Accounts." *Id.* This request is not clearly relevant to the current phase of discovery and is denied.

RFP No. 56 requests "[a]ll documents that show or track the following information for any of the Phase 1 Accounts: (a) The attendees at each IOI Support program, session, call, conference, or meeting provided by an ABS or Outside Consultant; and (b) The cost of any dinners, lunches, or meals that were provided to attendees of each IOI Support program, session, call, conference, or meeting provided by an ABS or Outside Consultant." *Id*. Janssen argues that in an April 23, 2021 order, a duplicative request, relator's RFP No. 20, was denied. That request, however,

concerned national programs. (#120 ("Defendant need not produce aggregate national-level financial information relating to the scope, purpose, success, value, etc. of the national infusion business support program at this time."). In any case, asking Janssen to provide this information—for multiple IOI Support programs over twenty years—is overly burdensome at this phase of discovery and is denied.

RFP No. 57 requests "[a]ll documents concerning any presentation, resource, or program that was developed to be used in connection with any of the various types of IOI Support provided but ultimately was not approved for use by your Promotional Review Committee (or its equivalent), legal department, or compliance department." (#236-1 at 15.) This request seeks relevant materials and is allowed.

RFP No. 58 requests "[a]ll documents concerning the provision (directly or through an agent) of any service, advice, or education to physician practices, which is similar to any of the various types of IOI Support, as part of an effort to promote and/or support a medicine administered via infusion other than Remicade and Simponi ARIA." *Id.* Janssen argues that this request is tangential to relator's allegations as it seeks discovery on issues unrelated to the services at issue here. (#249 at 10). The court agrees. In seeking information about programs beyond IOI Support programs, this request exceeds the scope of discovery at this phase and is denied.

V. Conclusion.

Accordingly, for the reasons discussed above, relator's motion to propound additional RFPs (#233) is ALLOWED, and relator's motion to compel (#235) is ALLOWED in part and DENIED in part.

February 17, 2022

/s/ M. Page Kelley
M. Page Kelley
United States Magistrate Judge